REMARKS/ARGUMENTS

In response to the Office Action of August 24, 2004, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Support for Amendments/Claim Status

No new matter has been added by the amendments to the specification made herein.

A second substitute Sequence Listing has been added. Additionally, other amendments have been made that correspond with the second substitute Sequence Listing. The Sequence Listing and the amendments are discussed further in the section entitled "Alleged New Matter".

The disclosure of prior art, PCT/EP97/04396, at page 4 has been amended to correct a typographical error in the international application number. The corresponding international publication number has also been added.

A protocol in the experimental section of the detailed description has been amended to properly identify the trademark name, SEPHAROSE, using capitalization.

The abstract has been amended to remove the legal phraseology ("said").

No new matter has been added by the amendments to the claims made herein.

Claims 1, 36, 41 and 42 have been amended. Claims 2-35 were cancelled in the previous reply (filed on June 16, 2003). Claims 1 and 41-43 have been withdrawn from consideration. Claims 36-40 are under examination. Claims 1 and 36-43 remain pending in the instant application.

Claim 1 has been amended to specifically claim the biopolymer marker (SEQ ID NO:1). The term "biopolymer marker" is used throughout the originally filed specification, see, for example, page 1, line 7. Claim 1 has also been amended to indicate that the claimed biopolymer marker is separated from its naturally occurring state. The biopolymer marker is referred to as "isolated" at page 31, lines 9-12 of the originally filed specification.

Claim 36 has been amended to more clearly disclose the relationship between the presence of the claimed biopolymer marker (SEQ ID NO:1) and Type II diabetes. Claim 36 has also been amended to clearly indicate how the presence of the claimed biopolymer marker is determined from mass spectrum profiles. The changes to claim 36 find basis through-out the original disclosure, see, for example, page 17, lines 11-14, the paragraph bridging page 26 and 27 and Figure 2.

Claim 41 has been amended to correspond the recited sequence with the second substitute Sequence Listing.

Claim 42 has been amended to provide proper antecedent basis for the term "diagnostic kit".

Restriction

The Examiner has indicated that newly submitted claims 41-43 (submitted June 16, 2003) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 41-43 are drawn to a diagnostic kit that includes an antibody that binds to a specific peptide in order to provide a diagnosis of Type II diabetes. The Examiner further states that since applicants have received an action on the merits for the originally presented invention, the invention has been constructively elected by original presentation for prosecution on the merits. Thus, the Examiner has withdrawn claims 41-43 from consideration as being directed to a non-elected invention.

Request for Rejoining of Claims

Considering that claims 36-40 are limited to the use of an isolated biopolymer marker having SEQ ID NO:1, a search of these claims would encompass this specific biopolymer marker. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claim 1 in the instant application, which is currently drawn to a non-elected invention, under the decision in *In re Ochiai* (MPEP 2116.01) with claims 36-40 of the

elected invention, upon the Examiner's determination that the claims of the elected invention are allowable and in light of the overlapping search.

ALLEGED NEW MATTER

A) Objection to the Specification

The Examiner has objected to the amendment filed on June 16, 2003 under 35 USC 132 because it allegedly introduces new matter into the disclosure. The Examiner alleges that the added material which is not supported by the original disclosure is as follows: the disease specific marker consisting of amino acid residues 2-17 of SEQ ID NO:1 (page 27, last full paragraph and brief description of figure 1).

Applicants respectfully disagree with the Examiner's assertions. Originally filed claim 1 recites "sequence ID SSKITHRIHWESASLLR", a biopolymer marker having 17 amino acid residues. This is the peptide which was identified by SEQ ID NO:1 in the first Sequence Listing filed on April 19, 2002. Originally filed Figure 1 discloses a table of data collected from Type II diabetes patients. The sequence associated with the patients in Figure 1 was recited as SSKITHRIHWESASLL, a biopolymer marker having 16 amino acid residues. Figure 2, as originally filed, discloses a spectra pointing out the peak produced by the sequence recited as RSSKITHRIHWESASLLR, a biopolymer marker having 18 amino

acid residues. All three of these sequences are identified in the original disclosure as a fragment of Complement C3f having a molecular weight of 1998 daltons. The first amino acid residue, "R", shown in originally filed Figure 2 is not disclosed in the originally filed Sequence Listing (April 19, 2002). A substitute Sequence Listing was filed on June 16, 2003 to correct SEQ ID NO:1 such that the amino acid residue "R" was included within the sequence. The biopolymer marker, having 17 amino acid residues, was disclosed in the table of patient data shown in Figure 1 and thus was claimed in the amendment filed on June 16, 2003. All of these sequences were disclosed in the specification as originally filed. Additionally, they are all identified as the same peptide (fragment of C3f complement). Thus, Applicants respectfully assert that it is clear that no new matter was added to the specification.

However, in order to further prosecution Applicants herein provide a second substitute Sequence Listing (in both paper and computer-readable form) to replace the previously submitted substitute Sequence Listing filed on June 16, 2003. The second substitute Sequence Listing submitted herewith lists SEQ ID NO:1 without the first amino acid residue "R" as disclosed in Figure 2. SEQ ID NO:1 as listed in the second substitute Sequence Listing is the same as SEQ ID NO:1 as listed in the originally filed Sequence Listing (April 19, 2002). The claims, as amended herein, limit the biopolymer marker sequence to SSKITHRIHWESASLLR as originally

disclosed at page 27, line 18 of the instant specification. Thus, no new matter has been added by the second substitute Sequence Listing. The computer-readable form (CRF) of the second substitute Sequence Listing is identical to the paper copy of the second substitute Sequence Listing.

Additionally, all recitations referring to "amino acid residues 2-17 of SEQ ID NO:1" have been removed from the specification and the claims.

B) Rejection under 35 USC 112, first paragraph

Claims 36-40, as originally filed, stand rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement.

The Examiner alleges that the specification does not provide literal or adequate descriptive support for the recitation of "disease specific marker consisting of amino acid residues 2-17 of SEQ ID NO:1".

Applicants respectfully disagree with the Examiner's assertions. In addition to the reasons supplied above in section A, Applicants point out that amino acid residues 2-17 of SEQ ID NO:1 are physically present within any recitation of the fragments of SEQ ID NO:1 and thus are literally supported by the specification as originally filed.

However, in order to further prosecution, all recitations

referring to "amino acid residues 2-17 of SEQ ID NO:1" have been removed from the specification and the claims.

Accordingly, Applicants respectfully request that the above-discussed rejection under 35 USC 112, first paragraph now be withdrawn.

Rejections under 35 USC 112, second paragraph

Claims 36-40, as originally presented, stand rejected under 35 USC 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner asserts that claim 36, step b) is non-idiomatic and therefore, ambiguous in reciting "elucidation of discernible peptides".

The Examiner asserts that claim 36, step c) is non-idiomatic and therefore, ambiguous in reciting "peptides elucidated".

The Examiner asserts that claim 36, step c) is vague and indefinite in failing to recite a positive limitation in the claim in reciting "wherein recognition of a mass spectrum profile in the sample....is diagnostic for Type II diabetes".

Claim 36 has been amended to remove the phrases "elucidation of discernible peptides", "peptides elucidated" and "wherein recognition of a mass spectrum profile in the sample...is diagnostic for Type II diabetes". These phrases are not recited in

any of the remaining pending claims. Additionally, claim 36 has been amended to include some of the language suggested by the Examiner.

Accordingly, Applicants have now clarified the metes and bounds of the claims and respectfully request that all of the above-discussed rejections under 35 USC 112, second paragraph be withdrawn.

Rejection under 35 USC 112, first paragraph

Claims 36-40, as originally presented, stand rejected under 35 USC 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner asserts that the data set forth in Figure 1 only consists of a limited assay pool of 7 Type II diabetes patients who exhibit the presence of the claimed marker. There is no other evidentiary showing in the instant specification that one skilled in the art would have deduced that the claimed peptide fragment having 17 amino acid residues is a reactive marker that is diagnostic of Type II diabetes, because a population of 7 subjects is not a significant assay pool to draw one to such a conclusion. Additionally, the 7 subjects in Figure 1 from whom the samples were

obtained are known Type II diabetes patients; therefore, there is no representation of a population of previously unknown subjects that would have diagnosed of having Type II diabetes using the instant peptide fragment having SEQ ID NO:1.

The Examiner also cites prior art (Capiaumont et al.) which shows that the peptide consisting of amino acid residues 2-17 of SEQ ID NO:1, which is a fragment of human complement containing the HWESAS motif, also exhibits an indication of chronic renal failure. According to the Examiner, this is contrary to Applicants' deductive conclusion since an indication of chronic renal failure has been identified and equated with the claimed peptide fragment having SEQ ID NO:1 by prior art; hence, a diagnosis of chronic renal failure cannot be excluded from those who are deemed to have Type II diabetes using the instant peptide fragment having SEQ ID NO:1.

Applicants respectfully disagree with all of the Examiner's assertions.

The claims have been amended to clearly and concisely claim the presence of an isolated biopolymer marker having SEQ ID NO:1 in a patient sample displaying a peak profile at about 1998 daltons in a mass spectrum being indicative of a link to Type II diabetes. This determination does not require a 100% match or any other characteristic as a basis for comparison, it simply requires a peak to be present at about 1998 daltons, which evidences a link to Type

II diabetes. The instant specification fully supports the disease specific marker identified by SEQ ID NO:1, characterized as a fragment of complement C3f, having a molecular weight of about 1998 daltons as set forth in Figure 2 being indicative of an individual suffering from Type II diabetes (see page 27, line 17 to page 28, line 2).

Although Applicants believe that the instant specification fully supports the claim that an isolated peptide consisting of SEQ ID NO:1 is diagnostic for Type II diabetes, in the interest of compact, efficient prosecution Applicants have amended the claims to recite that the isolated peptide is linked to Type II diabetes.

According to the website dictionary.com the term "linked" refers to the condition of being associated with or connected to (see attached document as accessed from the website). The instant specification fully supports a connection and/or an association of the claimed peptide with Type II diabetes. The instant specification states at page 17, lines 11-14 that an objective of the invention is to evaluate samples containing a plurality of biopolymers for the presence of disease specific marker sequences which evidence a link to at least one specific disease state. The data presented in Figure 1 further supports the association of the claimed peptide with Type II diabetes.

The guidelines for a "test of enablement" indicate that if a statement of utility in the specification contains within it a

connotation of how to use, 35 USC 112 is satisfied. Furthermore, it has been established that the mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. The instant application discloses a biopolymer marker having SEQ ID NO:1 which is linked to Type II diabetes, such a biopolymer marker has not previously been shown to be linked to Type II diabetes. When a biopolymer marker is discovered to be associated with a disease state it carries with it a connotation of potential diagnostics and/or therapeutics. One of skill in the art of proteomics research would recognize this connotation and, contrary to the Examiner's assertion, would be able to deduce from the data in Figure 1 the potential diagnostics and/or therapeutics associated with the claimed peptide. Thus, based upon the statements in the instant paragraph, it is concluded that the Examiner's arguments are not sufficient to support the rejection under the guidelines of the "test for enablement" see MPEP 2164.01(c).

The Examiner repeatedly asserts that the data set shown in Figure 1 only consists of a limited assay pool of 7 Type II diabetes patients who exhibit the presence of the claimed marker.

However, the data was actually obtained from a large assay pool of over 500 patients. Figure 1 displays only that data which is relevant to the biopolymer marker claimed in the instant

application. Thus, contrary to the Examiner's assertions, Figure 1 does not consist only of a "limited assay pool". To further establish this point, Applicants provide herein a Declaration under 37 CFR 1.132 with attached Appendix A. Appendix A illustrates the link between the detected biopolymer of SEQ ID NO:1 which is positively identified through the instant method and a particular disease state (Type II diabetes). Appendix A was originally filed in applicants' application number 09/846,330 (publication number US 2002/0160420). This Appendix A does not represent results obtained from additional experimentation. This data was obtained from the original experiments performed at the time of the invention.

The data set illustrated in Figure 1 of the instant application can be found on page A11 of Appendix A at MW 1998. Appendix A records data obtained from a study of over 500 patients suffering from a variety of disease states, e.g. stroke, congestive heart failure, myocardial infarction, Type II diabetes, etc. The data set includes a patient history, disease and protein name, molecular weight and the identified peptide sequence found to be associated with the disease state. The PG publication (US 2002/0160420) states at paragraph [0123]:

Appendix A clearly illustrates patient specific samples obtained and the data used to formulate a library of proteomic materials having characteristics identifiable with both normal and

abnormal physiological conditions or predictive hallmarks thereof. Data which is exemplary of the information retrieved via the novel proteomic investigative techniques of the instant invention are set forth in Appendix A.

Additionally, for example, multiple fragments of complement C3f were positively identified in samples obtained from the patient labeled as TWH-002 by carrying out the instant method; the 1777 dalton fragment, page A8, the 1865 dalton fragment, page A11 and the 2021 dalton fragment, page A11 and the 1998 dalton fragment (SEQ ID NO:1), page A11. The presence of these four fragments in the same patient further evidences a link between the presence of complement C3f and a diagnosis of Type II diabetes.

The instant specification indicates at page 16, line 19 to page 17, line 6 that subsequent to the isolation of particular disease state marker sequences, as taught by the instant invention, the promulgation of various forms of risk-assessment tests are contemplated which will allow the physician to identify symptomatic patients before they suffer an irreversible event such as diabetes, kidney failure, and heart failure, and enable effective disease management and preventative medicine. Routine risk assessment tests generally include blood and urine analysis, x-rays, electrocardiogram (EKG), cardiac stress tests, computer assisted tomography (CAT) scans, magnetic resonance imagery (MRI), echocardiographic studies, Doppler analysis, angiograms,

electromyograph (EMG), electroencephalograph (EEG) and the like. All of these tests are well known in the diagnostic art to assist physicians in forming a definitive diagnosis, see related application 09/846,330, paragraph bridging pages 1 and 2.

Thus, Applicants submit that the specification does in fact teach that patients suspected of having Type II diabetes in which the claimed peptide was found to be present were followed up, or confirmed by other routine diagnostic tests. However, the intended purpose of the invention is to provide improved, alternative means for diagnosis of Type II diabetes which can easily be performed by an untrained individual without the need for additional testing. If "follow up" diagnostic methods are also required, then the diagnostic process is lengthened and the invention fails to fulfill its intended purpose.

The Examiner asserts at multiple locations in her Office Action that the 7 subjects in Figure 1 from whom the samples were obtained are known Type II diabetes patients and therefore there is no representation of a population of previously unknown subjects that would have been diagnosed with Type II diabetes using the instant peptide fragment having SEQ ID NO:1.

Applicants assert that no representation of a population of previously unknown subjects is required to use the claimed method. The data presented in Figure 1 and attached Appendix A clearly support the association of the biopolymer marker having SEQ ID NO:1

with Type II diabetes.

The Examiner cites an article, Capiaumont et al. Clinica Chimica Acta 293:89-103 2000, which allegedly shows that the claimed peptide of SEQ ID NO:1 was found to indicate renal failure. The Examiner then concludes that this article is contrary to Applicants' deductive conclusion since an indication of chronic renal failure cannot be excluded from those who are deemed to have Type II diabetes using the instant peptide fragment having SEQ ID NO:1.

Applicants respectfully submit that the Capiaumont et al. reference is not relevant to the claimed invention. Applicants' claims do not include or exclude the possibility of renal failure or any other condition in patients in which the claimed peptide is positively identified. The instant method simply requires that the claimed peptide be identified by a peak at about 1998 daltons in a mass spectrum profile of a patient sample to evidence a link to Type II diabetes. The data in Figure 1 and attached Appendix A fully support this link.

The Examiner uses the same arguments as presented immediately above (unknown subjects and prior art) to conclude that Applicants' previously filed 1.132 Declaration has a low probative value in supporting Applicants' conclusion that the peptide fragment having SEQ ID NO:1 is specific only for the diagnosis of Type II diabetes.

Applicants respectfully disagree with the Examiner's

arguments. In addition to the discussion above, Applicants note that the peptide fragment having SEQ ID NO:1 is not claimed to be specific only for the diagnosis of Type II diabetes. Applicants are only required to enable material which is claimed.

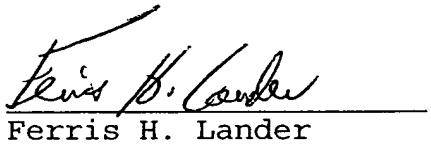
In conclusion, Applicants claim that the presence of SEQ ID NO:1 is indicative of a link to Type II diabetes; a statement which is enabled by the data presented in Figure 1, Appendix A and the Declaration filed on June 16, 2003. Applicants assert that one of ordinary skill in the art when reviewing the instant specification and Declarations would recognize how to use the claimed peptide as a marker for Type II diabetes. Thus, Applicants respectfully request that this rejection under 35 USC 112, first paragraph now be withdrawn.

CONCLUSION

In light of the foregoing remarks, amendments to the specification and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

If there are any additional fees due in connection with the filing of this amendment, please charge Applicant's Deposit Acct. No. 50-1803.

Respectfully submitted,



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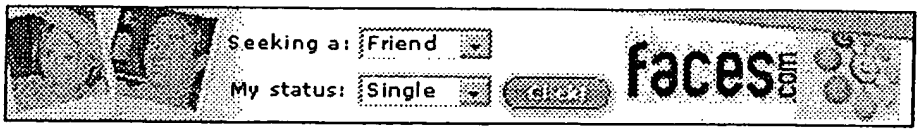

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link[1] Pronunciation Key (lĭngk)
n.

1. One of the rings or loops forming a chain.
2. a. A unit in a connected series of units: *links of sausage; one link in a molecular chain.*
   b. A unit in a transportation or communications system.
   c. A connecting element; a tie or bond: *grandparents, our link with the past.*
3. a. An association; a relationship: *The Alumnae Association is my link to the school's present administration.*
   b. A causal, parallel, or reciprocal relationship; a correlation: *Researchers have detected a link between smoking and heart disease.*
4. A cuff link.
5. *Abbr.* **li** A unit of length used in surveying, equal to 0.01 chain, 7.92 inches, or about 20.12 centimeters.
6. A rod or lever transmitting motion in a machine.
7. *Computer Science.* A segment of text or a graphical item that serves as a cross-reference between parts of a hypertext document or between files or hypertext documents. Also called **hotlink, hyperlink**.

v. **linked, link·ing, links**

v. tr.

1. To connect with or as if with a link: *linked the rings to form a chain.* See Synonyms at join.
2. *Computer Science.* To make a hypertext link in: *linked her webpage to her employer's homepage.*

v. intr.

1. To become connected with or as if with a link: *The molecules linked to form a polymer.*
2. *Computer Science.* To follow a hypertext link: *With a click of the mouse, I linked to the company's website.*

[Middle English `linke`, *of Scandinavian origin*; akin to Old Norse `hlekkr`, `*hlenkr`, from `*hlenkr`.]

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link'er *n.*

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link[2] [P] Pronunciation Key (lĭngk)
n.

A torch formerly used for lighting one's way in the streets.

[Possibly from Medieval Latin `linchinus, lichnus`, *candle*, from Latin `lychnus`, from Greek `lukhnos`, *lamp*. See `leuk-` in Indo-European Roots.]

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link

Whatever became of your high school prom king?

classmates.com

\Link\ (l[i^][ng]k), n. [Prob. corrupted from lint and this for lunt a torch, match, D. lont match; akin to G. lunte, cf. MHG. l["u]nden to burn. Cf. Lunt, Linstock.] A torch made of tow and pitch, or the like. --Shak.

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link

\Link\, n. [OE. linke, AS. hlence; akin to Sw. l["a]nk ring of a chain, Dan. l[ae]nke chain, Icel. hlekkr; cf. G. gelenk joint, link, ring of a chain, lenken to bend.] 1. A single ring or division of a chain.

2. Hence: Anything, whether material or not, which binds together, or connects, separate things; a part of a connected series; a tie; a bond. ``Links of iron." --Shak.

Source: *Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.*

link

\Link\, v. i. To be connected.

No one generation could link with the other. --Burke.

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\Link\ (l[i^][ng]k), v. t. [imp. & p. p. Linked (l[i^][ng]kt); p. pr. & vb. n. Linking.] To connect or unite with a link or as with a link; to join; to attach; to unite; to couple.

All the tribes and nations that composed it [the Roman Empire] were linked together, not only by the same laws and the same government, but by all the facilities of commodious intercourse, and of frequent communication. --Eustace.

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link

\Link\, n. [See Linch.] 1. A hill or ridge, as a sand hill, or a wooded or turfy bank between cultivated fields, etc. [Scot. & Prov. Eng.]

2. A winding of a river; also, the ground along such a winding; a meander; -- usually in pl. [Scot.]

The windings or ``links" of the Forth above and below Stirling are extremely tortuous. --Encyc. Brit.

3. pl. Sand hills with the surrounding level or undulating land, such as occur along the seashore, a river bank, etc. [Scot.]

Golf may be played on any park or common, but its original home is the ``links" or common land which is found by the seashore, where the short close tuft, the sandy subsoil, and the many natural obstacles in the shape of bents, whins, sand holes, and banks, supply the conditions which are easential to the proper pursuit of the game. --Encyc. of Sport.

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link

n 1: the means of connection between things linked in series [syn: nexus] 2: a fastener that serves to join or link; "the walls are held together with metal links placed in the wet mortar during construction" [syn: linkup, tie, tie-in] 3: the state of being connected; "the connection between church and state is inescapable" [syn: connection, connectedness] [ant: disjunction] 4: a connecting shape [syn: connection, connexion] 5: a unit of length equal to 1/100 of a chain 6: (computing) an instruction that connects one part of a program or an element on a list to another program or list 7: a channel for communication between groups; "he provided a liaison with the guerrillas" [syn: liaison, contact, inter-group communication] 8: a two-way radio communication system (usually microwave); part of a more extensive telecommunication network [syn: radio link] 9: an interconnecting circuit between two or more locations for the purpose of transmitting and receiving data [syn: data link] v 1: make a logical or causal connection; "I cannot connect these two pieces of evidence in my mind"; "colligate these facts"; "I cannot relate these events at all" [syn: associate, tie in, relate, colligate, link up, connect] [ant: decouple] 2:

connect, fasten, or put together two or more pieces; "Can you connect the two loudspeakers?"; "Tie the ropes together"; "Link arms" [syn: connect, tie, link up] [ant: disconnect] 3: be or become joined or united or linked; "The two streets connect to become a highway"; "Our paths joined"; "The travelers linked up again at the airport" [syn: connect, link up, join, unite] 4: link with or as with a yoke; "yoke the oxen together" [syn: yoke]

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link

1. <file system> hard link or symbolic link.

2. <hypertext> hyperlink.

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LINK: in Acronym Finder

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link: in CancerWEB's On-line Medical Dictionary

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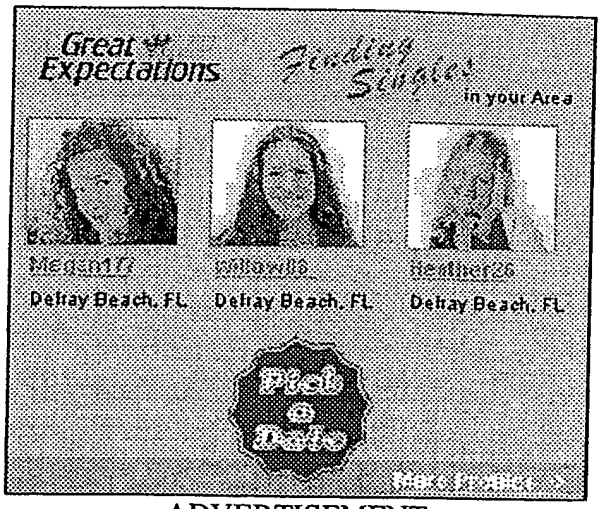

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